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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

SEPRACOR INC. and UNIVERSITY OF  
MASSACHUSETTS,

Plaintiffs and  
Counterclaim Defendants,

v.

GEOPHARMA, INC. and  
BELCHER PHARMACEUTICALS INC.,

Defendants.

Case No. 08-cv-945-MLC-TJB

Consolidated No. 07-cv-4213-MLC-TJB

**ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS GEOPHARMA, INC.  
AND BELCHER PHARMACEUTICALS, INC. TO PLAINTIFFS' COMPLAINT**

Defendants GeoPharma, Inc. and Belcher Pharmaceuticals, Inc. (collectively "Belcher"), hereby answer the Complaint (the "Complaint") filed by Plaintiffs Sepracor Inc. and University of Massachusetts (collectively "Plaintiffs") as follows:

### **Nature of the Action**

1. Belcher admits that the Complaint purports to state an action for infringement of U.S. Patent No. 7,214,683 (“the ‘683 patent”) and U.S. Patent No. 7,214,684 (“the ‘684 patent”) under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* Belcher admits that Belcher Pharmaceuticals, Inc. submitted an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”) for approval to commercially market generic desloratadine 5 milligram tablets before expiration of the ‘683 and ‘684 patents. Belcher lacks sufficient information to form a belief as to the truth or falsity of the allegation that the ‘683 and ‘684 patents are owned by Sepracor Inc. and University of Massachusetts, and therefore denies the same. Belcher denies the remaining allegations in paragraph 1 of the Complaint.

### **Parties**

2. Belcher is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint and therefore denies the same.

3. Belcher is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint and therefore denies the same.

4 Belcher admits that GeoPharma, Inc. is a Florida corporation having a place of business at 6950 Bryan Dairy Road, Largo, Florida 33777. Belcher denies the remainder of the allegations set forth in paragraph 4 of the Complaint. Nevertheless, Belcher waives the defense as permitted under Rule 12 by virtue of Belcher’s Answer and Affirmative Defenses to the Complaint.

5. Belcher admits that Belcher Pharmaceuticals, Inc. is a Florida corporation and a wholly-owned subsidiary of GeoPharma, Inc., having a place of business at 6911 Bryan Dairy Road, Largo, Florida 33777. Belcher denies the remainder of the allegations set forth in

paragraph 5 of the Complaint. Nevertheless, Belcher waives the defense as permitted under Rule 12 by virtue of Belcher's Answer and Affirmative Defenses to the Complaint.

### **Jurisdiction and Venue**

6. Admitted.

7. Belcher denies each and every allegation contained in paragraph 7 of the Complaint. Nevertheless, Belcher waives the defense as permitted under Rule 12 by virtue of Belcher's Answer and Affirmative Defenses to the Complaint.

8. Belcher denies each and every allegation contained in paragraph 8 of the Complaint. Nevertheless, Belcher waives the defense as permitted under Rule 12 by virtue of Belcher's Answer and Affirmative Defenses to the Complaint.

9. Belcher denies each and every allegation contained in paragraph 9 of the Complaint. Nevertheless, Belcher waives the defense as permitted under Rule 12 by virtue of Belcher's Answer and Affirmative Defenses to the Complaint.

### **The Patents In Suit and the Clarinex® Drug Products**

10. Belcher admits that the '683 patent is entitled "Compositions of Descarboethoxyloratadine." Belcher admits that the '683 patent indicates on its face that it was issued on May 8, 2007. Belcher denies that the '683 patent was properly issued and that it is valid. Belcher admits that Exhibit A to the Complaint appears to be a copy of the '683 patent, but lacks sufficient information to verify its authenticity. Belcher lacks sufficient information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 10 of the Complaint, and therefore denies each and every remaining allegation in paragraph 10 on that basis.

11. Belcher admits that the '684 patent is entitled "Methods for the Treatment of Allergic Rhinitis." Belcher admits that the '684 patent indicates on its face that it was issued on May 8, 2007. Belcher denies that the '684 patent was properly issued and that it is valid. Belcher admits that Exhibit B to the Complaint appears to be a copy of the '684 patent, but lacks sufficient information to verify its authenticity. Belcher lacks sufficient information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 11 of the Complaint and therefore, denies each and every remaining allegation in paragraph 11 on that basis.

12. Belcher admits that, according to the electronic records of the FDA, the '683 and '684 patents are identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" in association with Clarinex® 5 milligram desloratadine tablets. Belcher denies the remaining allegations in paragraph 12 of the Complaint.

#### **Acts Giving Rise to this Action**

13. Belcher admits that Belcher Pharmaceuticals, Inc. sent Sepracor a letter ("Notification Letter") notifying Sepracor that it had submitted ANDA 78-355 pursuant to section 505(j) of the Federal Food, Drug and Cosmetic Act in order to obtain approval to engage in the commercial manufacture, use or sale of generic tablets containing 5 milligrams desloratadine. Belcher lacks sufficient information to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 13 of the Complaint, and therefore denies each and every remaining allegation in paragraph 13 on that basis.

14. Belcher admits that Belcher Pharmaceuticals, Inc. submitted ANDA 78-355 to the FDA for approval to engage in the commercial manufacture, use or sale of generic tablets

containing 5 milligrams desloratadine. Belcher denies the remaining allegations in paragraph 14 of the Complaint.

15. Belcher admits that the Notification Letter states that in Belcher's opinion and to the best of its knowledge, the '683 and '684 patents are invalid. Belcher denies the remaining allegations in paragraph 15 of the Complaint.

16. Denied.

**Count I – Alleged Infringement of the '683 Patent by Belcher**

17. Belcher incorporates its responses to paragraphs 1-16 of the Complaint as though fully set forth herein.

18. Denied.

19. Denied.

20. Denied.

21. Denied.

**Count II – Alleged Infringement of the '684 Patent by Belcher**

22. Belcher incorporates its responses to paragraphs 1-21 of the Complaint as though fully set forth herein.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

**Response to Prayer for Relief**

Belcher denies that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs A through M of the Complaint.

## **AFFIRMATIVE DEFENSES**

Belcher alleges and asserts the following affirmative defenses in response to the allegations in the Complaint.

### **First Affirmative Defense**

1. The manufacture, use, offer for sale, sale or importation of the product described in Belcher's ANDA 78-355 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '683 patent and/or the '684 patent.

### **Second Affirmative Defense**

2. The claims of the '683 patent and/or the '684 patent are invalid for failure to comply with one or more of the requirements of 35 U.S.C. §§ 102, 103, 112 and/or for double patenting.

### **Third Affirmative Defense**

3. The Complaint fails to state a claim upon which relief can be granted.

### **Fourth Affirmative Defense**

4. The Complaint fails to state a claim for willful infringement.

### **Fifth Affirmative Defense**

5. Belcher reserves all affirmative defenses under Fed. R. Civ. P. 8(c), the Patent Laws of the United States, and any other defenses that may now exist or in the future be available based on discovery.

WHEREFORE Belcher demands judgment dismissing Plaintiffs' Complaint with prejudice, finding this case exceptional under 35 U.S.C. § 285 and awarding Belcher its reasonable attorneys' fees and costs of suit, and awarding Belcher any further and additional relief as the Court may deem just and proper.

Dated: May 2, 2008

RESPECTFULLY SUBMITTED,

/s/ Jeffrey A. Cohen

Jeffrey A. Cohen, Esquire (JC7673)

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**Jury Demand**

Belcher requests a jury trial on all issues so triable.

/s/ Jeffrey A. Cohen

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Dated: May 2, 2008

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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

I hereby certify that the matter in controversy is related to another case involving defendants Belcher Pharmaceuticals, Inc. and GeoPharma, Inc., namely *Schering Corporation v. Zydus Pharmaceuticals, USA, Inc., et al.*, 06-4715 (MLC)(TJB) and *In re Desloratadine Patent Litigation* MDL 1851, 07-3930 (MLC)(TJB), and several other matters involving Plaintiffs herein and other defendants, which have been consolidated into *Sepracor Inc., et al. v. Sun Pharmaceutical Industries, Inc., et al.*, 07-4213 (MLC)(TJB).

/s/ Jeffrey A. Cohen  
Jeffrey A. Cohen, Esquire

Dated: May 2, 2008